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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,371	12/05/2000	Tsukasa Seya	49927	2244

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	21

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/601,371	Seya et al.
Examiner	**Art Unit**
Prema Mertz	1646

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Feb 21, 2003*.

2a) [X] This action is **FINAL**. 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *11-14* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *11-14* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [X] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [X] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [X] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). 14
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

1. Claims 1, 3-5 have been canceled in Paper No. 20, 2/21/03 an claims 2, 6-10 have been canceled previously. New claims 11-14 (Paper No. 20, 2/21/03), are under consideration.

The substitute Supplemental Information Disclosure Statement/ PTO 1449 submitted is acknowledged and has been considered.

2. Receipt of applicant's arguments and amendments filed in Paper No. 20 (2/21/03) is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 20, 2/21/03:

(i) the rejection of claims 1, 3-5 under 35 U.S.C. § 101.

4. Applicant's arguments filed in Paper No. 20 (2/21/03), have been fully considered but were persuasive in part. The issues remaining and new issues, are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim objections

6. Claim 14 is objected to because of the following informalities:

Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Claim 14 is improperly dependent on claim 13 which is itself a multiple dependent claim. See MPEP.

§ 608.01(n). However, the claim has been further treated on the merits. Acting on the merits of this claim does not relieve the applicants of their responsibility to correct nor will such correction prevent the Examiner from making this Office action final.

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 11-14 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 4-8 of the previous Office action (Paper No. 18, 8/13/02) and Paper No. 6 (3/14/01) and Paper No. 12 (11/15/01).

7a. With respect to the written description rejection, Applicants argue that the rejection is obviated by the amendments herein. However, contrary to applicants arguments, claim 11 is a genus claim. According to the specification, the specification has only described a cytokine inducer M161Ag protein of SEQ ID NO: 2. The specification and claim do not indicate what distinguishing attributes are shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 2. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general,

guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the recitation of M161Ag alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus of protein molecules.

Furthermore, with respect to the 35 U.S.C. § 112, first paragraph scope of claims rejection, the issue here is the breadth of claims 11-14 in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.
To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is d described in the instant application but a substantial

inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed naturally-occurring SEQ ID NO:2 sequence, which are required for functional and structural integrity of those proteins. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce a cytokine inducer protein which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those

embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that all cytokine inducer proteins will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably alter the disclosed sequence with any reasonable expectation that the resulting protein will have the desired functions.Therefore Applicants have not presented enablement commensurate in scope with the claims.

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 11-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite for the recitation of M161Ag because the metes and bounds of this term are indefinite.

Claim 13 recites the limitation "the induced cytokines" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the N-terminal thereof" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 is rejected as indefinite insofar as it is dependent on claim 11 for its limitations.

Claim Rejections - 35 USC § 102

9a. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto et al (1995).

This rejection is maintained for reasons of record set forth at pages 8-9 of the previous Office action (Paper No. 18, 8/13/02).

Applicants argue that the 1995 Matsumoto reference does not teach that the M161Ag protein disclosed in the prior art reference induces cytokine production. Applicants argue that based on the Matsumoto et al, 1998 publication, the M161Ag is a dual functional protein in which the cytokine inducing function is separate from the complement activating function. Furthermore, Applicants argue that based on the Lien et al, 1998 reference, the cytokine induction by M161Ag is mediated by Toll-like receptor 2 signaling pathway and not by the human complement pathway. However, contrary to Applicants' arguments, the instant M161Ag protein is indistinguishable from the prior art M161Ag protein.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP. 2112.01.

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." see In re Papesch, 315 F. 2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Therefore, since the protein in the reference appears to be consistent with the protein which is claimed, the claimed polypeptide would be the same as the polypeptide of the reference. Since the Office does not have the facilities for examining and comparing Applicants' protein with the protein of the prior art, the burden is upon the applicant to show the novel difference between the protein of the instant application and that of the Matsumoto (1995) reference.

9b. Claims 11-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsumato et al (1997).

This rejection is maintained for reasons of record set forth at page 9 of the previous Office action (Paper No. 18, 8/13/02).

Applicants argue that the 1997 Matsumoto et al reference provides no teaching that the C3 activation and deposition on human cells induce cytokine production. However, contrary to applicants' arguments, for the reasons set forth in paragraph 9a above, the instant M161Ag protein is indistinguishable from the prior art M161Ag protein.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior

art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP. 2112.01.

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." see In re Papesch, 315 F. 2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Therefore, since the protein in the reference appears to be consistent with the protein which is claimed, the claimed polypeptide would be the same as the polypeptide of the reference. Since the Office does not have the facilities for examining and comparing Applicants' protein with the protein of the prior art, the burden is upon the applicant to show the novel difference between the protein of the instant application and that of the Matsumoto (1995) reference.

9c. Claims 11-14 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 9-157295 (1997).

This rejection is maintained for reasons of record set forth at page 9 of the previous Office action (Paper No. 18, 8/13/02).

Applicants argue that the JP 9-157295 reference provides no teaching that the C3 activation and deposition on human cells induce cytokine production. However, contrary to applicants'

arguments, for the reasons set forth in paragraph 9a above, the instant M161Ag protein is indistinguishable from the prior art M161Ag protein.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP. 2112.01.

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." see In re Papesch, 315 F. 2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Therefore, since the protein in the reference appears to be consistent with the protein which is claimed, the claimed polypeptide would be the same as the polypeptide of the reference. Since the Office does not have the facilities for examining and comparing Applicants' protein with the protein of the prior art, the burden is upon the applicant to show the novel difference between the protein of the instant application and that of the Matsumoto (1995) reference.

9d. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rawadi et al (1996).

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action (Paper No. 18, 8/13/02).

Applicants argue that the cytokine inducing ability of M161Ag could not be anticipated by Rawadi et al. However, contrary to applicants' arguments, for the reasons set forth in paragraph 9a above, the instant M161Ag protein is indistinguishable from the prior art M161Ag protein.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP. 2112.01.

"From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." see In re Papesch, 315 F. 2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Therefore, since the protein in the reference appears to be consistent with the protein which is claimed, the claimed polypeptide would be the same as the polypeptide of the reference. Since the Office does not have the facilities for examining and comparing Applicants' protein with the protein of the prior art, the burden is upon the applicant to show the novel difference between the protein of the instant application and that of the Matsumoto (1995) reference.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 10, 2003